EXHIBIT 37

Food and Drug Administration Office of Regulatory Affairs

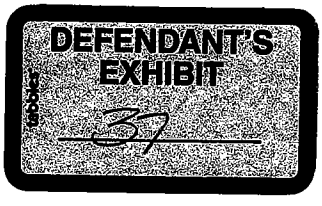
Collection Report

For Sample Number: 162746

This is an accurate reproduction of the original electronic record as of 04/02/2008

Payment Amount	Payment Method	704(d) Sample	702(b) Portion	Collector's Name
$0.00	No Charge	No	No	Lillian C Lopez

Name of Signer	Date & Time of Signature			Meaning
Lillian C Lopez	03/24/2008	04:10 PM	ET	Collector



Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 462746

TD Sample Number: **Import Sample Number**

This is an accurate reproduction of the original electronic record as of 09/23/2008

Sample Class: Normal Everyday Sample
Survey Sample

Sample Origin: Domestic
Sample Type: Official

Sample Basis: Surveillance
Collecting District: SAN-DO

Home District:

Orig C/R and Records To: SAN-DO

Collection PACs: 56008A

Product Name: Digoxin (Cardiotonic); Human - Rx/Single Ingredient; Delayed Release Tablets

Product Description: Digoxin Tablets, 125 mcg, RX, single ingredient

Collection Reason: FY 2008 Low Cost Generic Drug Sample Survey 2008-800 (CP 7356.008). Analyze for Uniformity of Dosage Units; Dissolution; Identification

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Lab: NRL **Split Num** 0 **Date Received:** 03/26/2008 **Date Out of Lab:** 09/23/2008

District Conclusion:

District Conclusion Made By:

District

Disposition Reason:

Disposition Authorized By:

Disposition Authorized Date

Performing Org	PAC	LID	PAF	Compliance No	Lab Class-Description	Laboratory Status
NRL-DCB-G	56008A		DRT		1 - In Compliance	Completed

Lab Conclusion

The product meets specifications for Identification, Dissolution, and Content Uniformity.

Lab Conclusion Date **Lab Conclusion Made By**

09/23/2008 Mathew,Samuel K

RECEIVED
OCT - 6 2008
FDA -- SJN
COMPLIANCE BRANCH

FLAG Original

ANALYST WORKSHEET	1. PRODUCT: DIGITEK (DIGOXIN TABLETS,USP) 125mcg(0.125 mg)		2. SAMPLE NUMBER: 462746
3. SEALS: ☒ INTACT ☐ BROKEN ☐ NONE	4. DATE REC'D: 4/3/08	5. RECEIVED FROM: Elvis Leslie	6. DISTRICT OF LABORATORY: NRL

7. DESCRIPTION OF SAMPLE

One brown, paper bag officially sealed, "462746 03/25/08 Lillian C. Lopez CST ", containing two product cartons identified " 462746 03/21/08 LCL Sub 1 of 2 " and " 462746 03/21/08 LCL Sub 2 of 2 ", respectively. An FDA 525 is attached to the sample.

8. NET CONTENTS			9. LABELING	
☐ NOT APPLICABLE ☒ NOT DETERMINED ___ UNITS EXAMINED	DECLARE/UNIT AMOUNT: 180 tablets FOUND: ___ % OF DECLARED: ___		1 ORIGINAL(S) SUBMITTED 1 COPIES SUBMITTED ☐ NONE	

10. SUMMARY OF ANALYSIS

Container: White, rectangular, cardboard carton approximately 14.5 cm x 6.5 cm x 7 cm. Carton contains 6 intact, rectangular, foil, blister packs. Each pack is in a separate, white, plastic case and contains 30 tablets.

Labeling: Carton has a commercially-printed, rectangular, paper, stick-on label. Commercially-printed product insert is inside carton. Plastic case has a similar commercially-printed label.

Code: " Lot No.: 7P964 " and " Exp. Date: 4/09 " printed on the carton label and the back of each blister pack.

Product: Round, flat and bevel, solid, light-yellow tablet. Tablet is unmarked and unscored on one side. Opposite side is 1/2-scored with markings "B" and "145". Tablet is approximately 6.5 mm in diameter.

Analysis: Identification, Dissolution, and Content Uniformity.

Method: USP 30 - NF 25, p. 1943.

Results: See general continuation sheet page 2.

11. RESERVE SAMPLE

Original, brown, paper bag officially sealed " 462746 9/22/08 Valentino Fiorella Analyst" containing one open and one intact product carton. Open carton is additionally identified " VF 4/3/08 ". Plastic case with used blister pack containing 8 tablets is identified " #462746 4/3/08 VF Sub 2 of 2 ". Sample returned to the sample custodian.

12.a. ANALYST SIGNATURE (Broke Seal ☒)	13. WORK-SHEET CHECK	a. BY: S. Mathew
b.		b. DATE: 9/23/08
c.	14. DATE REPORTED: 9/23/08	

FORM FDA 431 (5/84) PREVIOUS EDITION IS OBSOLETE

ATTACHMENTS : A (pp. 1 - 27), B

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VF 9/22/08

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 462746

RESULTS:

Identification

The retention time of the major peak in the chromatogram of the *sample preparation* corresponds to that in the chromatogram of the *standard preparation*. Complies

Content Uniformity

(See computer printout pages 6 - 7 for complete results)

Range: 97.1 % to 102.1 %; Average (X): 99.4 %;

RSD: 1.8 %; s: 1.74

Acceptance Value (AV) = 4.2 %

(Limit: AV ≤ 15.0 % unless otherwise specified in the individual monograph)

Dissolution

(See least squares line fitting pages 11 - 12 for complete results)

Range: 93.4 % to 111.6 % ; Avg.: 105.0 %

(Limit: Each unit is NLT Q+5% (Q=80%) for 6 units tested (Stage 1))

ANALYST(S) Valentino Fiorella	ANALYST NO. 113	PAGE 2 OF 12 PAGES

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DIGOXIN TABLETS
(USP 30-NF 25, p.1943)

Reference Std:
USP Digoxin RS # 1200000-05, Lot O0B096, dried in vacuum at 105°C for 1 hour prior to use. For quantitative applications, use a value of 0.961 mg of digoxin per mg on the dried basis.

Reagents: Fisher Scientific Acetonitrile, Lot 073938 (Rec'd 11/1/07)
Sigma Digoxigenin, Lot No. 016K3777 (Rec'd 2/6/08)

Filter: PALL Life Sciences Acrodisc 25 mm Syringe Filter with 0.45 um Nylon Membrane, Lot A10529577

Identification

The retention time of the major peak in the chromatogram of the *sample preparation* corresponds to that in the chromatogram of the *standard preparation*. Complies

Content Uniformity

Mobile Phase: Water/Acetonitrile (74/26)

System Suitability Solution
(Balance: Cahn C-31 Microbalance, FDA No. 5004472 - QA by G.Lehr on 1/14/08)

4.025 mg USP Digoxin RS + 4.122 mg Digoxigenin

----> 100.0 ml Diluted Alcohol

Standard Solution 1 (CCV)
(Balance: Cahn C-31 Microbalance, FDA No. 5004472 - QA by G.Lehr on 1/14/08)

2.522 mg USP Digoxin RS ----> 100.0 ml Diluted Alcohol

25.0 ml
----------> 50.0 ml Diluted Alcohol

Standard Solution 2 (ICV/Check Std.)
(Balance: Cahn C-31 Microbalance, FDA No. 5004472 - QA by G.Lehr on 1/14/08)

2.505 mg USP Digoxin RS ----> 100.0 ml Diluted Alcohol

25.0 ml
----------> 50.0 ml Diluted Alcohol

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 462746

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Content Uniformity

Sample Solution
For each of 10 tablets tested:

1 tablet (0.125 mg) ----> 10.0 ml Diluted Alcohol ----> Filter

Chromatographic System
(See pp. 2 - 3 ,Attachment A for chromatograms)

Resolution (R)

$R = \frac{2(t2 - t1)}{w1 + w2} =$ 20.7 [Limit: R is NLT 4.0]

Theoretical Plates(N)

$N = 16(t/w)^2 =$ 5315 [Limit: N is NLT 1200]

Tailing Factor (T)

$T = [W_{0.05}/2f] =$ 1.1 [Limit: T is NMT 2.0]

Relative Std. Deviation (RSD)
(See computer calculation, page 5)

RSD = 0.18 % [Limit: RSD is NMT 2.0%]

Standard 2 Calculation (ICV/Check Std.)
(See pp. 3 - 8 ,Attachment A for chromatograms)

$$\% \text{ Digoxin} = \frac{\text{Area Std.2}}{\text{Area Std.1}} \times \frac{\text{Std 1 Wt.}}{\text{Std 1 Dilution}} \times \frac{\text{Std 2 Dilution}}{\text{Std 2 Wt.}} \times 100$$

Area Std.1 = Avg.area of 5 std. injections. (See computer calculation, p. 5)
Std.Wt.1 = (2.522 mg) (0.961) = 2.424 mg
Std.Wt.2 = (2.505 mg) (0.961) = 2.407 mg

$$\% \text{ Digoxin} = \frac{675184}{678145} \times \frac{2.424 \text{ mg}}{200.0 \text{ ml}} \times \frac{200.0 \text{ ml}}{2.407 \text{ mg}} \times 100 = 100.3\%$$

GENERAL CONTINUATION SHEET	PRODUCT	SAMPLE NO.
	Digoxin Tablets (0.125 mg)	462746

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Standard 1 Calculation (CCV)
(See pp. 3 - 7 and page 27, Attachment A for chromatograms)

$$\% \text{ Digoxin} = \frac{\text{Area Std.1(9)}}{\text{Area Std.1}} \times \frac{\text{Std 1 Wt.}}{\text{Std 1 Dilution}} \times \frac{\text{Std 1 Dilution}}{\text{Std 1 Wt.}} \times 100$$

Area Std.1 = Avg. area of 5 std. injections. (See computer calculation, p. 5)
Area Std.1(9) = Area of Std.1, Injection 9. (See page 27, Attachment A)
Std.Wt.1 = (2.522 mg)(0.961) = 2.424 mg

$$\% \text{ Digoxin} = \frac{679031}{678145} \times \frac{2.424 \text{ mg}}{200.0 \text{ ml}} \times \frac{200.0 \text{ ml}}{2.424 \text{ mg}} \times 100 = 100.1\%$$

Calculations
(See computer printout pages 6 - 7 for complete results and pages 9 - 13, 22-26 Attachment A for 1 Sample chromatograms)
Area Std.1 = Avg.area of 5 std. injections. (See computer calculation, p. 5)
Std.Wt.1 = (2.522 mg)(0.961) = 2.424 mg

If 98.5% ≤ X ≤ 101.5%, then M = X

Range: 97.1 % to 102.1 %; Average(X): 99.4 %; RSD: 1.8 %; s: 1.74

Acceptance Value(AV) = M - X + ks

AV = (2.4)(1.74) = 4.18 %

(Limit: AV ≤ 15.0 % unless otherwise specified in the individual monograph)

General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 462746

Statistical Analysis of Data: Standard Solution 1 (CCV) 05/20/2008

Relative STD Deviation	**0.18 %**		
Standard Deviation	1202.05229		
Average (mean)	**678145.2**		
Number of entries	5		
Range	676751	To	679893

Data Entered:

676751
677360
678550
678172
679893

Analyst(s) Valentino Fiorillo	Analyst No. 113	Page 5 of 12 Pages

NRL FORM 431a - Statistics Worksheet Revised 5/17/01 RCC

General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 462746

Content Uniformity

05/21/2008

No. of Units Examined	10
Standard Weight	2.424 mg.
Standard Dilution	200
Sample Dilution	10

Data Entered:

Unit #1	707447	STD #1	678145
Unit #2	687826	Blank	0
Unit #3	691235		
Unit #4	695615		
Unit #5	678836		
Unit #6	681037		
Unit #7	711029		
Unit #8	714211		
Unit #9	692266		
Unit #10	689421		

CONTENT UNIFORMITY RESULTS:

	FOUND (mg/tablet)	DECLARED	% of DECLARED
UNIT #1	0.126	0.125	101.1
UNIT #2	0.123	mg/tablet	98.3
UNIT #3	0.124		98.8
UNIT #4	0.124		99.5
UNIT #5	0.121		97.1
UNIT #6	0.122		97.4
UNIT #7	0.127		101.7
UNIT #8	0.128		102.1
UNIT #9	0.124		99.0
UNIT #10	0.123		98.6
AVG.	**0.124**		**99.4**

OFFICIAL LIMITS:	90.0	%	TO	105.0	%
No. of Units Examined	10				
RANGE	**97.1**	%	TO	**102.1**	% of Declared
UNITS >=85 BUT <=115 % of Avg. Limit :					10
UNITS >=75 BUT <85 OR >115 BUT <=125 % of Avg. Limit :					0
UNITS <75 OR >125 % of Avg. Limit :					0
REL. STD. DEV. :	**1.8** LIMIT <= 6.0%				

mg/unit = (R_spl * std_wt * spl_dil) / (R_std * std_dil * 1 unit)

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General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 462746

Statistical Analysis of Data:

Content Uniformity
Standard Deviation

05/21/2008

Relative STD Deviation	1.75 %		
Standard Deviation	1.74		
Average (mean)	99.36		
Number of entries	10		
Range	97.1	To	102.1

Data Entered:

101.1
98.3
98.8
99.5
97.1
97.4
101.7
102.1
99
98.6

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NRL FORM 431a Statistics Worksheet Revised 5/17/01 RCC

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO 462746

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Dissolution

Medium: 0.1N HCl, 500 ml (37.0°C ± 0.5°C)
Apparatus 1: 120 rpm
Time: 60 minutes
Instrument: Distek Dissolution Apparatus #1, FDA No. 1218
(QA by F.Maldonado on 7/7/08)
Instrument: Shimadzu Fluorescence Spectrophotometer, FDA# 5004459
(QA by V.Fiorella on 7/1/08)

Reagents: Sigma L-Ascorbic Acid, Lot 10K0256 (Rec'd before 4/10/06)
Sigma-Aldrich 30% H_2O_2, Batch# 04824AH (Rec'd 4/3/08)
Fisher Scientific Methanol, Lot 081717 (Rec'd 5/27/08)
Fisher Scientific HCl, Lot 068102 (Rec'd 5/4/07)

Filter: PALL Life Sciences Acrodisc Premium 25 mm Syringe Filter with 0.45 um GHP Membrane, Lot 21688684

Ascorbic acid-Methanol Solution

(Mettler Toledo AX205, FDA No. 5099471 - QA by D.Dai on 7/10/08)

201.9 mg Ascorbic acid ----> 100.0 ml MeOH

Hydrogen peroxide-Methanol Solution

Stock Solution: 2.0 ml 30% H_2O_2 ---> 100.0 ml MeOH (Refrigerate)

Working Solution: 2.0 ml Stock ---> 100.0 ml MeOH

Standard Solutions

(Mettler Toledo AX205, FDA No. 5099471 - QA by D.Dai on 7/10/08)

Stock Solution

25.09 mg USP Digoxin RS ---> 500.0 ml Dilute Alcohol (4 in 5)

10.0 ml
----------> 100.0 ml Dilute Alcohol (4 in 5) [0.005 mg/ml]

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 462746

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Working Standard Solutions

Standard Solution	ml Stock Solution	ml Dissolution Medium	Final Concentration (mg/ml)
20%	1.0	100.0	0.00005
40%	2.0	100.0	0.00010
60%	3.0	100.0	0.00015
80%	4.0	100.0	0.00020
100%	5.0	100.0	0.00025

Test Solution (6 tablets tested; 0.125 mg/tablet)

1 tablet ---> 0.1N HCl, 500 ml ---> Filter [0.00025 mg/ml]

Procedure

Test Prep.: 1.0 ml Test Solution *(Prepared in duplicate)*
+ 1.0 ml Ascorbic acid-Methanol Solution
+ 5.0 ml HCl
+ 1.0 ml Hydrogen peroxide-Methanol Solution
----> Glass-stoppered flask

Std. Preps.: 1.0 ml of each Working Std. Solution
+ 1.0 ml Ascorbic acid-Methanol Solution
+ 5.0 ml HCl
+ 1.0 ml Hydrogen peroxide-Methanol Solution
----> Glass-stoppered flask

Blank Prep.: 1.0 ml Dissolution Medium
+ 1.0 ml Ascorbic acid-Methanol Solution
+ 5.0 ml HCl
+ 1.0 ml Hydrogen peroxide-Methanol Solution
----> Glass-stoppered flask

Procedure

After 2 hours (FDA Timer# 1678 - QA by A.Vargas on 1/18/08), measure the fluorescence of each preparation at an emission wavelength of about 485 nm and an excitation wavelength of about 372 nm correcting each reading for the blank.

Plot a standard curve of Fluorescence vs. % Dissolution.

Determine the % dissolution of digoxin for each Test Solution from the graph.

GENERAL CONTINUATION SHEET	PRODUCT Digoxin Tablets (0.125 mg)	SAMPLE NO. 462746

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General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 462746

Least Squares Line Fitting

09/17/2008

The Line Fitting used is Y = mX + b

with m = 0.02381

and b = -0.0498

Correlation Cofficient = 0.999204448

Data Entered:

	X	y	LSLF y	% Deviation
20% Std.	20	0.452	0.4264	6.004
40% Std.	40	0.874	0.9026	3.169
60% Std.	60	1.352	1.3788	1.944
80% Std.	80	1.892	1.855	1.995
100% Std.	100	2.324	2.3312	0.309

Extrapolated Data:

	X	Y
Tablet 1-Test 1	93.86	2.1850
Tablet 1-Test 2	92.94	2.1630
Tablet 2-Test 1	104.19	2.4310
Tablet 2-Test 2	101.04	2.356
Tablet 3-Test 1	110.45	2.58
Tablet 3-Test 2	110.07	2.571

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Results

See least squares line fitting calculation, pages 11 - 12, and Attachment B for spectra.

Name	EM @ 485 nm	Corrected EM @ 485 nm
Blank	-0.008	0
20% Std. Solution	0.444	0.452
40% Std. Solution	0.866	0.874
60% Std. Solution	1.344	1.352
80% Std. Solution	1.884	1.892
100% Std. Solution	2.316	2.324
Tablet 1-Test 1	2.177	2.185
Tablet 1-Test 2	2.155	2.163
Tablet 2-Test 1	2.423	2.431
Tablet 2-Test 2	2.348	2.356
Tablet 3-Test 1	2.572	2.58
Tablet 3-Test 2	2.563	2.571
Tablet 4-Test 1	2.582	2.59
Tablet 4-Test 2	2.617	2.625
Tablet 5-Test 1	2.56	2.568
Tablet 5-Test 2	2.559	2.567
Tablet 6-Test 1	2.401	2.409
Tablet 6-Test 2	2.344	2.352
100% Std. Solution	2.379	2.387

Tablet	% Dissolution 1	% Dissolution 2	Avg. % Dissolution
1	93.86	92.94	93.40
2	104.19	101.04	102.62
3	110.45	110.07	110.26
4	110.87	112.34	111.61
5	109.95	109.9	109.93
6	103.27	100.87	102.07
AVG			104.98

[Limit: Each unit is NLT Q + 5% (Q=80%) for 6 units tested (Stage 1)]

General Continuation Sheet	Product: Digoxin Tablets (0.125 mg)	Sample No. 462746

Least Squares Line Fitting

09/17/2008

The Line Fitting used is Y = mX + b

with m = 0.02381

and b = -0.0498

Correlation Cofficient = 0.999204448

Data Entered:

	x	y	LSLF y	% Deviation
20% Std.	20	0.452	0.4264	6.004
40% Std.	40	0.874	0.9026	3.169
60% Std.	60	1.352	1.3788	1.944
80% Std.	80	1.892	1.855	1.995
100% Std.	100	2.324	2.3312	0.309

Extrapolated Data:

	X	Y
Tablet 4-Test 1	110.87	2.5900
Tablet 4-Test 2	112.34	2.6250
Tablet 5-Test 1	109.95	2.5680
Tablet 5-Test 2	109.90	2.567
Tablet 6-Test 1	103.27	2.409
Tablet 6-Test 2	100.87	2.352

Analyst(s) Valentino Fiorillo	Analyst No. 113	Page 12 of 12 Pages

Least Squeres Line Fitting Worksheet Revised 5/17/01 RCC